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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,244

01/18/2005

Scott K. Kuwada

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7587

23859 7590 05/29/2008  
NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER

PAGONAKIS, ANNA

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,244	<b>Applicant(s)</b> KUWADA, SCOTT K.	
	<b>Examiner</b> ANNA PAGONAKIS	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 and 53-72 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 16-17, 19-20, 22-25, 33, 41 and 58-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 8-15, 18, 21, 26-32, 34-40, 42, 53-57 and 64-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

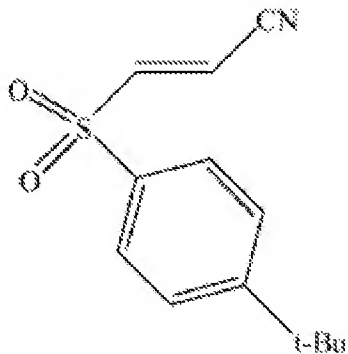
#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7 sheets, 5/16/2005; 3 sheets, 8/20/2004</u> . | 6) <input type="checkbox"/> Other: _____  |



### DETAILED ACTION

Applicant's election without traverse of colon cancer as the disease and BAY 11-7085 (depicted below):



in the reply filed on 3/7/08 is acknowledged. Claims 16-17, 19-20, 33 and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Accordingly, 2-7, 22-25, 58-63 claims have been withdrawn, 43-52 have been cancelled and no claims have been added or amended.

Claims 1, 8-15, 18, 21, 26-32, 34-40, 42, 53-57, 64-72 are presently under examination and are the subject of this Office Action.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-15, 18, 21, 26-32, 34-40, 42, 53-57, 64-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izban et al. (Human Pathology, Vol. 31, No. 12, 2000) and Khan et al (US 7,175,679).

Izban et al. teach the use of the elected compound, BAY 11-7085 for its use as a NF-kappa B inhibitor (abstract).

Khan et al. teach that inhibition of NF-kappaB modulates the COX pathway and this inhibition of NF kappa B can be therapeutically useful in diseases in which COXs are involved such as cancer, especially colorectal cancer (column 69).

One of ordinary skill in the art at the time of the invention would have found in prima facie obvious to employ the NF kappa B inhibitor, BAY 11-7085, taught by Izban et al. in patient suffering from colorectal cancer as a means for treatment of the disease. Such a person would have been motivated to do so because the prior art of Khan et al. clearly recognizes the contribution that a NF-kappa B inhibitor has in treating colorectal cancer. Further, the skilled artisan would have had a reasonable expectation of success in treating colorectal cancer because the inhibition of NF-kappa B, which is known to play a role in colorectal cancer, would have been treatable, or at least slowed by a known NF-kappa B inhibitor such as BAY 11-7085, taught by Izban et al.

With respect to claims, 9-15, 21, 26-28, it is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject

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matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

With respect to claims 64-72, the determination of a dosage, mode of administration, addition or removal of pharmaceutically acceptable excipients and slats that have the optimum therapeutic index is well within the purview of one having ordinary skill in the art. Accordingly, the artisan would have been motivated to determine optimum pharmaceutically acceptable excipients in order to get maximum effect of the active agent. Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

### **Conclusion**

No claims are found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP  
5/21/2008

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614